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1617  
Patent Application  
Attorney Docket No. PC10734A US

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By \_\_\_\_\_

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Irene Grantham

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:  
FRANK ROBERT BUSCH ET AL.

APPLICATION NO.: 09/881,322

Examiner: San Ming R Hui

FILING DATE: JUNE 14, 2001

Group Art Unit: 1617

TITLE: The Use Of Growth Hormone Secretagogues  
To Treat Systemic Lupus Erythematosus and  
Inflammatory Bowel Disease

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Hon. Commissioner for Patents  
Washington, D.C. 20231

Sir:

AMENDMENT AND REPLY UNDER 37 C.F.R. §1.111

In response to the Office Action dated August 13, 2002 for the above referenced application, Applicants make the following amendments and remarks:

AMENDMENTS

In the claims:

Please cancel claims 18-29 and 31-61 without waiver or prejudice. Applicants reserve the right to pursue the non-elected subject matter in divisional applications.

REMARKS

Amendment and reconsideration of this application as amended is respectfully requested. Claims 1-61 are pending in this application. Claims 1-61 are subject to a restriction requirement under 35 USC §121.

RESTRICTION REQUIREMENT

In the present Office Action, the Examiner has stated that the present application contains inventions or groups of inventions that are distinct from each other. The Examiner has designated these inventions as Groups I to VI and has assigned certain claims to each group. The claims directed to Groups II, IV, V and VI have been cancelled without waiver or prejudice to filing divisional applications.

According to the Examiner, the inventions listed as Groups I to VI do not relate to a single invention as each group is allegedly distinct. Therefore, Applicants are required to elect a single invention to which the claims must be restricted.

Applicants elect with traverse Group I, claims 1-17, drawn to a method of treating systemic lupus erythematosus employing growth hormone secretagogues classified in class 514, subclass 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258 and 290-314. Applicants traverse this restriction requirement for the reason that it is applicants belief the inventions of Groups I and III are related. Applicants submit that the claims of Groups I and III are related as the claims both relate to methods of treating systemic lupus erythematosus employing growth hormone secretagogues classified in class 514, subclass 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258 and 290-314. The Examiner has stated that the inventions in Groups I and III are not related because they operate by different modes as the invention of Group I operates by employing a single agent whereas the invention of Group III operates by employing two agents. Applicants agree with the Examiner that in Group I the method employs the growth hormone secretagogue alone while in Group III the method employs the growth hormone secretagogue in combination with a secondary agent selected from methotrexate, dapsone, a glucocorticoid or an antimalarial agent. However, applicants submit this difference is not sufficient by itself to require restriction. Applicants submit that the methods of treatment as claimed in Groups I and III have been disclosed as capable of being used together in the specification. For example, at page 30, lines 8-27 of the specification it is disclosed that a second therapeutic agent such as methotrexate, dapsone, glucocorticoids or antimalarials may be used in combination with the growth hormone secretagogue. Because the methods of treatment in groups I and III have been disclosed as capable of being used together to serve the same function of treating systemic lupus erythematosus and to provide

the same therapeutic effect applicants submit that the claims of groups I and III are directed to the same invention. Applicants further submit that examination of the claims in groups I and III would not place an undue burden on the Examiner as both groups relate to the treatment of systemic lupus erythematosus employing growth hormone secretagogues classified in class 514, subclass 215, 230.5, 226.5, 248, 249, 250, 252.02, 252.04, 252.06, 252.12, 256, 257, 258 and 290-314, either alone as in group I or in combination with methotrexate, dapsone, a glucocorticoid or an antimalarial as in group III.

Given the above, Applicants hereby request reconsideration and withdrawal of the present restriction requirement directed to Groups I and III.

ELECTION OF SPECIES

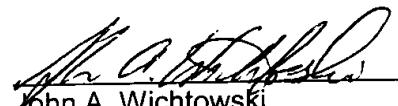
Also, the Examiner states that in addition to election of one of the above groups, applicants are required to elect a single species for the group.

Applicants elect with traverse the single species in claim 10.

In view of the foregoing, reconsideration of this application and its early allowance are respectfully requested.

Respectfully submitted,

Date: 28 August 2002



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